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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/188,661	11/09/1998	S. WARD CASSCELLS III	1441-00109	4595

7590 02/13/2003

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EXAMINER

WINAKUR, ERIC FRANK

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/188,661

Applicant(s)

CASSELLS III ET AL.

Examiner

Eric F Winakur

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003 and 19 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 24-30 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22,31-34 and 36-39 is/are allowed.
- 6) ☒ Claim(s) 1-21,23 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 24 - 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.
2. Applicant's traversal with regard to Groups I, II, and IV is noted. As Applicant's arguments are found persuasive, Examiner hereby withdraws the restriction requirement involving these Groups, and will examine claims 1 - 23 and 31 - 39.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1 - 21, 23, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to claim 1, it appears that the term "the" should be inserted before "detection" (line 10); use of the term "optionally" (line 16) renders the scope of the claimed subject matter unclear; it appears that the phrase "a vessel" (line 19) should read "the vessel"; it is unclear whether Applicant intends the recitation following the term "whereby" to merely refer to an intended result or to define a claim limitation. With regard to claims 9 and 23, use of the term "optionally" renders the scope of the claimed subject matter unclear. With regard to claim 35, it is unclear what Applicant considers the preamble of the claim and what is considered the body of the claim, as the transition phrase "comprising" is recited twice in the claim.

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Allowable Subject Matter

5. The following is a statement of reasons for the indication of allowable subject matter: Applicant cites numerous prior art references. In addition, Andersson-Engels et al. teach a fluorescence method that includes detecting atherosclerotic plaque. None of the prior art teaches or suggests optically measuring two chemical parameters associated with inflamed vulnerable atherosclerotic plaque at multiple sites on a vessel wall and analyzing the measurements, as set forth in the claims. Further the prior art does not teach identifying a predictive level of risk for sites or groups of sites on a vessel wall by identifying and correlating areas having $\text{pH} < 7.2$, an amount of oxidized collagen indicative of a thin or weak cap, red microthrombi, or which have taken up or sequestered indicator dye. The prior art does not teach or suggest an improved method of detecting vulnerable atherosclerotic plaque wherein at least two analytes associated with activated macrophages are measured or an improved method of differentiating atherosclerotic plaque by analyzing for indicia of actively metabolizing cells.

6. Claims 22, 31 - 34, and 36 - 39 are allowed.

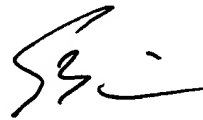
7. Claims 1 - 21, 23, and 35 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F Winakur whose telephone number is 703/308-3940. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703/308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are 703/305-3590 for regular communications and 703/305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0858.



Eric F Winakur
Primary Examiner
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February 10, 2003